

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

UNITED STATES OF AMERICA,)
)
Plaintiff,)
)
v.)
)
AN UNDETERMINED QUANTITY OF)
½ OUNCE BOTTLES OF AN ARTICLE OF)
DRUG, LABELED IN PART:)
)
(bottle))
)
“*** NC Solution™ (anti-fungal solution))
tolnaftate 1% 15 ml (1/2 oz) ***”)
)
and)
)
all other article of drug for human or)
animal use, including active and inactive)
pharmaceutical components and in-process)
materials and components, and all articles)
of food, food ingredients, and in-process)
materials, in any size and type of container,)
labeled or unlabeled (regardless of)
identification as to lot, batch, control)
number, production date, or expiration date),)
which are located anywhere on the premises)
of General Therapeutics Corp., 3650)
Windsor Place, St. Louis, Missouri, or)
elsewhere within the jurisdiction of this)
Court, to which are affixed labels bearing,)
among other things, the name and address)
of the manufacturer, packer, or distributor)
located outside of the State of Missouri, or)
which are otherwise determined to have)
originated outside of the State of Missouri,)
)
Defendants,)
)

No. 4:07-CV-1847 CAS

and)
)
GENERAL THERAPEUTIC)
CORPORATION,)
)
Claimant.)

ORDER AND DECREE OF CONDEMNATION AND DESTRUCTION

On October 29, 2007, the United States of America (“Plaintiff” or “United States”) filed a Verified Complaint of Forfeiture (“Complaint”) in this Court against the above-captioned articles (the “Articles”) in the possession of General Therapeutic Corporation (“General Therapeutic” or “Claimant”), located at 3650 Windsor Place, St. Louis, Missouri. The Complaint alleged that the in rem defendants proceeded against were adulterated and therefore subject to condemnation and destruction. 21 U.S.C. §§ 321(p), 355(b), 351(a)(2)(A), 351(a)(2)(B), and 342(a)(4).

Pursuant to the Warrant of Arrest in rem issued by this Court, the United States Marshal for this District seized the articles on October 31, 2007. On November 8, 2007, the United States submitted a return to the Court that identified 465 separate Articles that were seized. On December 27, 2007, General Therapeutic intervened and filed a Verified Statement of Interest with respect to 236 of the Seized Articles (the “Claimed Articles”). The 236 Claimed Articles were specified in Exhibit A to General Therapeutic’s Verified Statement of Interest.

On March 13, 2008, this Court issued a Default Judgment of Forfeiture with respect to the 229 Seized Articles that were not identified in General Therapeutic’s Statement of Interest. The United States is currently in the process of contracting for the destruction of those articles.

On May 6, 2008, General Therapeutic filed a “Dismissal of Claim” that sought to dismiss the Statement of Interest that it filed on December 27, 2007. The Dismissal of Claim cited Rule 41(c)

of the Federal Rules of Civil Procedure, but was not accompanied by any legal argument or memorandum of law. The United States opposes General Therapeutic's attempt to withdraw its claim on the basis that nothing in Rule G of the Supplemental Rules for Admiralty, Maritime, and Asset Forfeiture Actions or in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 ("FDCA"), permits a party to dismiss a claim after filing claims or answers. The United States asserts that even if General Therapeutic is permitted to withdraw its claim, 21 U.S.C. § 334(e) requires an award of costs against it, citing United States v. Articles of Drug . . . Penapar VK, 458 F. Supp. 687, 689 (D. Md. 1978) ("Penapar VK"). Finally, the United States argues that if General Therapeutic is permitted to withdraw its claim, the United States would be deprived of receiving a judgment with res judicata effect. Claimant General Therapeutic did not file a reply in support of its Dismissal of Claim and the time to do so has passed.

Discussion.

As a threshold matter, the Court construes Claimant General Therapeutic's Dismissal of Claim as a motion to withdraw its claim. The United States' first objection to the motion to withdraw is that neither Rule G of the Supplemental Rules nor Rule 41(c), Fed. R. Civ. P., permit the withdrawal of a claim in an in rem proceeding. The Court agrees that Rule 41(c) is inapplicable, as that rule governs dismissal of claims by a plaintiff, and the Court has found no forfeiture cases in which Rule 41 was applied. Cf. United States v. All Articles of Drug Consisting of Finished and In-Process Products, 242 F.Supp.2d 617, 620 (D. Minn. 2002) ("All Articles") (holding that Rule 41(a), Fed. R. Civ. P., is inapplicable to withdrawal of claims by intervening party in in rem forfeiture case). Nonetheless, courts have granted intervening parties leave to withdraw claims in civil forfeiture cases.

See, e.g., All Articles, 242 F.Supp.2d at 621, 622; United States v. 374/100 Pound Burlap Bags, 1989 WL 36948, *1 (E.D. Pa. Apr. 13, 1989).

With respect to the United States' second objection, a person who intervenes as a claimant in a forfeiture action under the FDCA becomes liable for costs under 21 U.S.C. § 334(e). See, e.g., Hipolite Egg Co. v. United States, 220 U.S. 45, 59-60 (1911); United States v. An Article of Food Consisting of 12 Barrels . . . Lumpfish Roe, 477 F. Supp. 1185, 1193 (S.D.N.Y. 1979). The statute provides, "When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article." 21 U.S.C. § 334(e). Courts have consistently held that the cost requirements of section 334(e) apply "to any unsuccessful claimant, including one who attempts to withdraw prior to entry of a condemnation decree." 374/100 Pound Burlap Bags, 1989 WL 36948, *1 (citing Penapar VK, 458 F. Supp. at 689); see also All Articles, 242 F.Supp.2d at 621 ("an intervening party may withdraw its claim, as long as it pays the costs of the condemnation as required by 21 U.S.C. § 334(e)."); United States v. 302 Cases of Frozen Shrimp, 25 F.Supp.2d 1352, 1357 (M.D. Fla. 1998) (stating that a claimant may withdraw from a case, but withdrawal does not waive liability for costs).

The United States' final objection is that General Therapeutic should not be permitted to withdraw its claim because to do so would deprive the United States of a res judicata judgment with respect to any subsequent action where the parties and the issues are the same. The United States cites several cases that discuss the res judicata effect of judgments in forfeiture cases, but none hold that the government is entitled to a judgment with such an effect. The United States cites Hipolite Egg Co., 220 U.S. 45, United States v. 14 105 Pound Bags . . . Mineral Compound, 118 F. Supp. 837 (D. Idaho 1953), and United States v. 4 Cans, etc., Master Liquid, 127 F. Supp. 243 (N.D. Iowa

1955). In Hipolite Egg Co., the Supreme Court merely held that if a party voluntarily intervenes in a forfeiture action, the court has jurisdiction to enter an in personam action against it for costs. 220 U.S. at 59-60. The other cases do not establish a right to a res judicata judgment, but simply recognized that a prior judgment was res judicata of certain issues under the circumstances of those forfeiture proceedings. In 14 105 Pound Bags . . . Mineral Compound, the court held that where another district court had ruled in an earlier action involving the same claimant and seized product that the product was not effective in treating or preventing bloat of livestock, the claimant was estopped from contesting in the subsequent action the issue whether the product was effective in treating or preventing bloat. 118 F.Supp. at 839. Similarly, in United States v. 4 Cans, etc., Master Liquid, the court held that where prior cases involving the same parties held that claimant's hog medicine was misbranded and of no aid or value in preventing or curing a hog disease, the claimant could not relitigate the issues of misbranding or efficacy of the hog medicine in the subsequent action. 127 F. Supp. at 244-46. These cases merely apply general res judicata principles that a party cannot relitigate issues which were fully litigated and decided against it in prior actions. The cases do not support the United States' objection that a claimant cannot withdraw a claim in order to avoid a res judicata judgment in an in rem forfeiture action.¹

The United States also cites United States v. Various Articles of Device . . . Sporidicin, 814 F. Supp. 31, 32 (E.D. Tenn. 1992), in which the district court held that permitting the claimant to withdraw its claim would deprive the government of a res judicata judgment. In support of its ruling,

¹The All Articles case, decided by a district court in the Eighth Circuit, also rejected the United States' reliance on Hipolite Egg Co., United States v. 14 105 Pound Bags . . . Mineral Compound, and United States v. 4 Cans . . . Master Liquid, observing that "there is far more recent authority to show that an intervening party may withdraw its claim, as long as it pays the costs of the condemnation as required by 21 U.S.C. § 334(e)." 242 F.Supp.2d at 621.

the district court cited United States v. Sandoz Pharmaceuticals Corp., 894 F.2d 825 (6th Cir.), cert. denied, 498 U.S. 810 (1990). In Sandoz, the Sixth Circuit approved the application of collateral estoppel principles in an in rem forfeiture action to preclude a claimant from relitigating the issue whether two of its drugs were “new drugs” within the meaning of 21 U.S.C. § 321(p), where that issue had been decided against the claimant in a prior action. The Sandoz case is similar to the cases discussed above, and does not support the proposition that a claimant cannot withdraw its claim in order to avoid a res judicata judgment. Because the Sandoz decision was the sole authority cited in Sporicidin with respect to res judicata, the Court finds Sporicidin unpersuasive.

The court in Sporicidin also relied on a fairness argument that the government had invested substantial amounts of time in the case by answering a motion to dismiss, participating in scheduling conferences and negotiations, and filing a motion for summary judgment, which would be wasted if the claimant were allowed to withdraw. 814 F.Supp. at 32. No dispositive motions have been filed in the instant case. Cf. All Articles, 242 F.Supp.2d at 621 (declining to follow Sporicidin and distinguishing it on the basis that in Sporicidin, the government’s summary judgment motion had been argued and was before the court for decision when the claimant sought to withdraw its claim).

Conclusion.

For the foregoing reasons, the Court concludes that Claimant General Therapeutic’s motion to withdraw its claim should be granted over the United States’ objections, but General Therapeutic will bear the costs of condemnation and destruction as required by 21 U.S.C. § 334(e).

Accordingly,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 334. Venue is proper in this District under 21 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1).

2. Claimant General Therapeutic Corporation's Motion for "Dismissal of Claim" is **GRANTED**, and the claim is hereby withdrawn. [Doc. 31] General Therapeutic Corporation remains responsible for costs of condemnation and destruction allowable under 21 U.S.C. § 334(e).

3. The United States has already published notice regarding all of the Seized Items. See Doc. 20. Now that General Therapeutic Corporation has withdrawn its claims, and no other claimants have come forward, the allegations of the Verified Complaint stand uncontradicted in the record, and the Court hereby finds that all of the Claimed Articles are adulterated as alleged in the Complaint and therefore subject to condemnation and destruction.

4. The Claimed Articles, as described in further detail in Exhibit A to General Therapeutic Corporation's Statement of Interest, violate the Act in the following ways: (a) certain of the Claimed Articles are drugs that are adulterated under the Act, 21 U.S.C. § 351(a)(2)(A), while held for sale after shipment in interstate commerce, in that they have been held under insanitary conditions whereby they may have become contaminated with filth; (b) certain of the Claimed Articles are drugs that are adulterated under the Act, 21 U.S.C. § 351(a)(2)(B), in that the methods used in and the facilities and controls used for their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with CGMP; and (c) certain of the Claimed Articles are foods that are adulterated under the Act, 21 U.S.C. § 342(a)(4), while held for sale after

shipment in interstate commerce, in that they have been held under insanitary conditions whereby they may have become contaminated with filth.

5. The Claimed Articles are hereby condemned pursuant to 21 U.S.C. § 334 and forfeited to the United States. The United States Marshal for the Eastern District of Missouri shall destroy forthwith the condemned Articles and make due return to this Court. Destruction shall be in a manner that complies with the requirements of applicable federal and state environmental laws.

6. Within twenty (20) calendar days after all of the Seized Articles are destroyed by the United States Marshal, the United States shall provide an invoice to General Therapeutic Corporation that identifies all costs and expenses incurred by the United States with respect to the Claimed Articles that are due under 21 U.S.C. § 334(e). General Therapeutic Corporation shall pay the United States for these costs no later than ten (10) calendar days after receiving the invoice.


7. Within thirty (30) calendar days after all of the Seized Articles are destroyed by the United States Marshal, the United States shall provide the Court with a notice stating that the destruction is complete as well as a bill of costs regarding any unpaid costs and expenses incurred with respect to the Claimed Articles that it believes are recoverable under 21 U.S.C. § 334(e), that General Therapeutic Corporation has not already paid as discussed in paragraph 6 above, and any legal arguments in support thereof. After reviewing any bill of costs and opposition thereto, the Court will enter a final judgment disposing of all claims in this action.

8. General Therapeutic Corporation shall at all times, until the Seized Articles have been destroyed, ensure that FDA representatives, representatives of the United States Marshals Service, or any contractors acting in support of the United States have free and unencumbered access to the Seized Articles for the purpose of complying with this Order.

9. The Court retains jurisdiction to issue such further decrees and orders as may be necessary to enforce or modify this Order and for granting such other relief as may be necessary and appropriate for the proper disposition of this proceeding.

10. The United States' Motion to Compel Discovery Responses is **DENIED** as moot. [Doc. 30]

SO ORDERED:


CHARLES A. SHAW
UNITED STATES DISTRICT JUDGE

Dated this 29th day of May, 2008.